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Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-97-58

May 22, 1997

**Maxwell Freymuller, President
Florida Peanut Distributors
516 1/2 St. Petersburg Drive
Oldsmar, Florida 34677**

Dear Mr. Freymuller:

The State of Florida, Department of Agriculture and Consumer Services, visited your firm on April 21, 1997, and collected a survey sample of Mickey's Game Time Fresh Roasted Peanuts, packaged by your firm in six-ounce poly bags, for aflatoxin analysis. Our analysis revealed that no aflatoxins were found. The poly bag label for this product was forwarded to this office for review which reveals serious violations of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and the Food Labeling Regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101).

Our review of your six-ounce poly bag label for Mickey's Game Time Fresh Roasted Peanuts reveals the product is misbranded in that the label fails to bear nutrition labeling as required by Section 403(q)(1) of the Act and 21 CFR 101.9. This product is not exempt from this requirement under Section 403(q)(5) of the Act, and was labeled on or after May 8, 1996. We have no record in the official file that your firm has a small business exemption from the nutrition labeling requirements for any low-volume food products produced and labeled by your firm.

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies regarding food products labeled by your firm. Other label violations can also subject your food products to regulatory action. It is your responsibility to assure that all of your products are labeled in compliance with the Act, and the requirements of the Food Labeling Regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, Ext 263.

Sincerely,

A handwritten signature in cursive script, reading "Douglas D. Tolen". The signature is written in dark ink and is positioned above the printed name and title.

Douglas D. Tolen
Director, Florida District